

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2007/017122

International filing date (day/month/year)  
31.07.2007

Priority date (day/month/year)  
03.08.2006

International Patent Classification (IPC) or both national classification and IPC  
INV. G06F19/00

Applicant  
SMITHS MEDICAL MD, INC.

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA:



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Date of completion of  
this opinion

see form  
PCT/ISA/210

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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**Box No. II Priority**

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 1-24,26-37

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 1-24,26-37

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13<sup>ter</sup>.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☒ See Supplemental Box for further details

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	<u>25</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>25</u>
Industrial applicability (IA)	Yes: Claims	<u>25</u>
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The application does not meet the requirements of Article 6 PCT, because claims 1-24 and 26-37 are not clear. These claims, in particular the independent claims 1, 16, 26 and 32 are drafted in such unclear and vague manner and use unclear terms without a well recognized technical meaning, that it was not possible to unambiguously and clearly determine the extent of the subject-matter intended to be claimed in terms of technical features. In particular, the wordings "displaying a meter having two or more locations, each of the two or more locations representing a corresponding parameter value" and "an indicator having a selectable positional relationship to the meter" are not clear. Therefore, a meaningful search of their claimed subject-matter could not be carried out.

Independent claim 25 uses the unclear wording "a slider bar having a plurality of locations, each of the plurality of locations representing a corresponding parameter value". The technical features defined by this wording could not be determined.

However, it seems that the subject-matter intended to be claimed is the subject-matter of independent claim 25 without the unclear wording explained above. Hence, the search was carried out and this opinion was established based on claim 25 without the unclear wording "a slider bar having a plurality of locations, each of the plurality of locations representing a corresponding parameter value".

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 1 Reference is made to the following documents:  
D1: WO 2006/023636 A (MEDTRONIC INC [US]) 2 March 2006 (2006-03-02)  
D2: GB-A-2 312 055 (BAXTER INT [US]) 15 October 1997 (1997-10-15)  
D3: US 2003/163088 A1 (BLOMQUIST MICHAEL L [US]) 28 August 2003 (2003-08-28)  
D4: WO 2006/073400 A (ADVANCED MEDICAL OPTICS INC [US]; CLAUS MICHAEL J [US]) 13 July 2006 (2006-07-13)

- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 25 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 25.

The subject-matter of claim 25 differs from the teachings of D1 (see D1 at the abstract, Figures 56, 61, 83, 85, 92, 97-100 and paragraphs 11, 178, 190-192 and 198) in that:

- a slider bar is displayed,
- the slider bar including a warning region located along a portion of the slider bar,
- displaying an indicator movable along the slider bar to a selected position, the selected position corresponding to a parameter value,
- upon detection of movement of the indicator to a position within the warning region, issuing an alert.

D1 discloses that when the user selects a parameter which is outside of a predetermined acceptable value or range, then a warning is generated. Hence, the difference is merely the visual presentation in the form of a slider bar with a warning region and a movable indicator.

However, the manner in which parameters are visually presented does not provide any technical effect but relates merely to aesthetic design, and hence it involves no inventive step (Article 33(3) PCT) since it solves no technical problem.

Furthermore slider bars with movable indicators to control parameters in medical devices were very well-known at time of priority of the application, see e.g. document D4.

- 3 What has been said above with reference to claim 25 in view of document D1 applies likewise in view of document D2 (see D2 at the abstract, the summary, Figures 4, 5 and 28, and page 13 lines 5-10 and page 26 l.24 - p.27 l.6).
- 4 What has been said above with reference to claim 25 in view of document D1 applies likewise in view of document D3 (see D3 at the abstract, the summary, Figure 9 and paragraph 71, and Figure 13 and paragraphs 125-129).

5 Final Remarks

It is not at present apparent which part of the application could serve as a basis for a new claim which might meet the requirements of the PCT.

In case the applicant regards some particular matter as fulfilling the requirements of the PCT, and/or when entering the European Phase, it is appropriate to file new claims which take account of the above comments. The applicant should in addition indicate the difference of the subject-matter of the new claims vis-à-vis the state of the art and the significance thereof, in particular in respect of the **technical** effect provided by said difference. He should furthermore give an indication of the objective **technical** problem to be solved in view of the prior art (based on the **technical** effect provided by the differences), i.e. the aim and task of modifying or adapting the prior art to provide the said **technical** effect. Some further information needs to be provided to demonstrate why such a modification would not be obvious to the person skilled in the art, taking into account of the prior art and the common general knowledge. This might be shown e.g. by indicating advantageous and unexpected effects of the next version of the claimed subject-matter.

**Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)**

<b>General information</b>	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
<b>Amending claims under Art. 19 PCT</b>	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
<b>Filing a demand for international preliminary examination</b>	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
<b>Filing informal comments</b>	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
<b>End of the international phase</b>	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
<b>Relevant PCT Rules and more information</b>	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003